Remarks

Claims 1–27 are pending in the captioned application.

The Examiner has required restriction under 35 U.S.C. § 121 and 372, as well as PCT Rule 13.1 to the "following inventions or groups of inventions, which are not so linked as to form a single general inventive concept":

I. Claims 1-6 and 13 are drawn to a product described as 'a set of libraries of genes.'

II. Claim 7-12 are drawn to a product described as a 'a set of library of proteins.'

III. Claims 14-23 are drawn to a method 'of identifying a protein.'

IV. Claim 24 is drawn to a product described as a protein having SEQ ID NO:1.

V. Claim 25 is drawn to a product described as a gene that codes for the SEQ ID NO:l protein.

VI. Claims 26-27 are drawn to a method 'of constructing randomized gene libaries [libraries].'

Specifically, the Examiner states, "the inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features..."

More specifically, the Examiner states "groups I, II, IV and V are drawn to different products (e.g., they differ in respect to their properties, their use and the synthetic methodology for making them) and Groups III and VI are drawn to different methods (e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods represent distinct subject matter..."

Further, the Examiner states, "groups I, II, IV and V do not share a technical feature because they represent distinct products. For example, Groups I and V are drawn to 'gene' products whereas Groups II and IV are drawn to 'protein' product. Each nucleic acid is structurally and functionally distinct from each polypeptide. Therefore, Groups I and V do not share a special technical feature with Group II and IV. Likewise Groups I and II are drawn to a 'library' whereas Group IV and V are not. The libraries of Groups I and II would not necessarily contain the individual members of Groups IV and V and, as a result, Groups I and II do not share a special technical feature with Groups IV and V either..."

The Examiner further states, "in addition, a technical feature does not link the methods of Groups III and VI. The methods do not share a special technical feature because they use different steps, require different reagents and/or will produce different results. In the instant case, Group III requires 'proteins' for binding partner 'screening'

whereas the method of Group IV requires 'nucleic acids' for the production of a 'gene library' and 'gene expression' products. Therefore, Groups III and VI do not share a special technical feature."

The Examiner continues, "furthermore, a technical feature does not link the methods of Groups III and VI with the products of Groups IV and V because the methods of Groups III and VI require a 'library' whereas Groups IV and V only disclose a 'single' molecule of protein or DNA. Therefore, Groups III-VI do not share a special technical feature."

The Examine summarizes, "finally, the technical feature linking Groups I and II with Groups III and VI appears to be that the method steps of Groups III and VI requires the library products of Groups II and VI, respectively. However, Choo et al. (Choo, Y.; Klug, A. 'Toward a code for the interactions of zinc fingers with DNA: Selection of randomized fingers displayed on phage' Proc. Natl. Acad. Sci. USA 1994, 91, 1163-1167) teaches the nucleic acid and protein libraries that Applicants claim in Groups I and II. For example, Choo et al discloses a library of nucleic acids (and also the proteins that they encode) that contain the sequence... FSXXXXLXXHX(R/K)THT wherein each X contains a library of codons composed of equal mixtures of (G/A/C)NN at each of the X positions constituting 'seven' libraries. Choo also discloses yet another nucleic acid library at the +9 position containing the randomized sequences of A(G/A)G..."

The Examiner concludes, "consequently, Groups I-III and VI are drawn to different special technical features. For example, Groups I and II are drawn to different products (e.g., they differ in respect to their properties, their use and the synthetic methodology for making them) and Groups III and VI are drawn to different methods (e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics."

The Examiner concludes, "groups I-VI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept."

The Examiner finally cites MPEP 1850 and 37 C.F.R. § 1.475 regarding unity of invention.

In response, Applicants elect, with traverse, the invention of Group III, namely claims 14–23. This election is made in response to the Examiner's requirement in accordance with 37 C.F.R. § 1.499 for Applicants "to elect a single invention to which the claims must be restricted."

The traversal is premised on the Applicants' position that, contrary to the Examiner's assertions, all the groups of the invention do relate to a single inventive concept under PCT Rule 13.1. Indeed, Applicants respectfully point out to the Examiner that the IPEA clearly did not arrive at the same position as the Examiner regarding the unity of an invention and examined all of the claims as a single invention. Contrary to what the Examiner has said, Applicants respectfully submit that the claims within Group I claim a set of libraries, which codes for proteins capable of specific binding interactions, which are the same proteins that are claimed in claims 7–12. The Examiner's attention is respectfully directed to the recitations of "A" and "B" that describe the protein coded for by the gene libraries in claim 1 or contained within the libraries of claim 7, the independent claims within the recited group.

Group III, claims 14–23, uses the set of protein libraries defined in claim 7, which clearly links this group to the previous groups. Group IV (claim 24), is a variant of the broader generic sequence recited in claim 6 and Group V is a gene which codes for this protein. As such, these two groups are connected back to the original group by the common inventive concept.

Finally, the method for constructing randomized gene libraries of Group VI is a method for producing randomized gene libraries as recited in previous claims. As such, Applicants respectfully submit that this is linked by the same inventive entity to the other groups.

While Applicants are mindful of the Examiner's distinctions raised above, Applicants respectfully assert that all of these groups are properly defined as a single inventive entity, as clearly recognized by the IPEA in issuing the Preliminary Examination Report. Thus, Applicants respectfully assert that all claims should be examined together, and traverse the restriction requirement.

In addition, the Examiner has required Applicants to elect species stating, "this application contains claims directed to more than one species..."

More specifically, the Examiner states, "if applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species below. Applicant must elect one species from each subgroup below. Claim 14 is generic."

Subgroup 1: Species of protein library (see claim 14)

Applicant must elect for purposes of search a ***single species*** of protein library that is 'representative' i.e., contains the same properties and or structural features as the rest of the library members.

In response, Applicants elect the set of proteins libraries recited in claim 11.

Subgroup 2: Species of binding partner (see claim 15)

Applicant must elect for purposes of search a ***single species*** of binding partner e.g., biotinylated polynucleotide, polynucleotide without biotinylation, etc.

Applicants object to this requirement, and respectfully assert that the degree of biotinylation of the polynucleotide is not at issue in the claim. Indeed, as defined at claim 9, lines 18–20, the term "polynucleotide" is something which Applicants respectfully assert is well understood. However, subject to this traverse, Applicants elect the species of a biotinylated polynucleotide.

Subgroup 3: Species of library set (see claim 10)

Applicant must elect for purposes of search a ***single species*** of protein e.g. 60 libraries in three groups of 20 libraries with specified amino acids at the 971 and b13 and +6 positions respectively.

Applicants fail to understand the difference between this and Subgroup 1 recited by the Examiner and request clarification before a species election is made.

Subgroup 4: Species of protein sequence (see claim 12)

Applicant must elect for purposes of search a ***single species*** of protein e.g., SEQ ID NO:2.

Again, Applicants fail to understand the difference between this and the requirement of Subgroup 1, and request clarification before a species election is made.

Subgroup 5: Species of observation (see claim 19)

Applicant must elect for purposes of search a ***single species*** of observation e.g., solid phase scintillation proximity assay.

In response, Applicants elect the species defined by claim 18, namely scintillation proximity assay.

Applicants respectfully submit that all the provisionally elected claims (13–23) read on the elected species, subject to clarification of the Examiner of his requirements in Subgroups 3 and 4.

The Examiner has also provided guidance as to the election of species in the other groups. Inasmuch as Applicants are traversing the Examiner's requirements of restriction of the claims, it is anticipated that Applicants may have to provide additional species elections after the Examiner has reviewed Applicants' traversal. However, at this point, Applicants are not ready to discuss the species restrictions of the other groups that the Examiner purports are all distinct inventions.

Additionally, in paragraph 10 of the Official Action, the Examiner cites a reference which he states, "teaches the nucleic acid and protein libraries that Applicants claim in Groups I and II."

As such is not being used as the basis for any objection, Applicants decline to comment on this reference at this point. If the Examiner utilizes this in a rejection of

some or all of the claims at a later date, Applicants will respond to the Examiner's objection.

In view of the foregoing, Applicants respectfully assert that the Examiner's restriction requirement is improper and should be withdrawn.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on August 8, 2003.

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